



Connecting a World of  
Pharmaceutical Knowledge

## New Jersey Chapter



ISPE Affiliates and Chapters Around The World

VOLUME 22, ISSUE 3

Summer 2015

# PHARMA BULLETIN

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### New Jersey Chapter Statement of Value

New Jersey ISPE is an organization of, and for, professionals in the ever changing Life Sciences Community. As such, we strive to provide value to our various constituencies – owners, consultants, designers, contractors, vendors, students and the un- and under-employed – in a number of critical areas:

Wide range of multi-level **Education and Training** whether you are a newly graduated student or a multi-decade veteran, to enable you to be more successful at your current or yet-achieved "ideal" responsibilities within the Life Sciences community;

Sharing of **Industry Trends** to enable you to provide greater value to your employer, colleagues and the Life Sciences community in general, as we all strive to succeed in a "do more with less" environment;

Providing a forum in which you can **share** your expertise, experiences, innovations and thoughts/dreams with your colleagues via seminars, articles, roundtables, task forces and so on, where you can positively contribute to the future of the Life Sciences community

Encouraging "work hard, play hard" opportunities where **socializing and networking** provide forums to informally expand your professional and personal network, resulting in friendships that last for decade.

## Upcoming Events

### Vaccines and BioTech Double Header

June 23, 2015 – Pfizer, Peapack, NJ

<https://www.eventbrite.com/e/vaccines-and-biotech-double-header-tickets-16805136616>

### Facility of the Future

September 30, 2015 – Bristol-Myers Squibb, Plainsboro, NJ

### Golf Outing

October 12, 2015 – The Knoll Country Club, Parsippany, NJ

## The President's Message



Newsletter Brief from the President ISPE New Jersey Chapter

So is it really summer already?? Incredible how quickly time flies...and the chapter business year is almost over, and still there is much to do. Special thanks to Amie Wengryn, our chapter manager who keeps us on track and the glue keeping us together.

In April, continuing our commitment and support to university students, the annual College Student Poster Contest was hosted by J&J New Brunswick. It included a presentation by Nancy Barber of BMS on the latest Trends in Product Development in the Pharmaceutical Industry, and a Young Professional interactive discussion by Tunde Babalola, also of BMS. It was a unique forum of industry professional and students, and received great feedback and generated interesting discussion. Among 16 candidates from Stevens, NJIT, Rutgers and Kings CC, our 4 student winners were: **Sana Nasim, Undergraduate, NJIT, Meng Li, Graduate/PhD NJIT, Yingxi ( Sally) Tang, Graduate/MS NJIT, Maitraye Sen, Graduate/PhD Rutgers.** They will represent the NJ Student Chapters at the International Competition in Philadelphia later this year. Many thanks to our industry judges: **Greg Cierpial, Roche, Regis Gautier, BMS, Gregory Krupa, Merck, Paul Malinowski, BD, Nishchal Chudasama, BMS, Michael Kelliher, Genzyme, Phillip Sumner, Pfizer, Richard McGreal, Merck, Jim Brinkman, Pfizer.** Also, many thanks to Alok Bhatt and Nandita Kamdar for all their help organizing and running the event.

In May, we held our annual Golf Outing at the Neshanic Valley Golf Course. Always a great event, and a great turnout. It was a very nice day .....even considering the wind (....at least it gave our members an excuse on their golf scores!). A great dinner followed, along with interesting event prizes. Many thanks to Rich Smith and David Kristjanson for all their help organizing and running this event.

On June 23rd, we are holding a meeting on Vaccines and Biotech Double Header at Pfizer Peapack. This includes a presentation by Dennis Gross, of the PA Drug Discovery Institute, on **Vaccines and Biologics Development** noting differences between drugs versus biologics, vaccine development, production case studies and clinical trials, and what to expect in the future. George Skillin of Pfizer will also present **Overall ISPE Facility of the Year Award Recipient and Category Winner for Operational Excellence**, how Pfizer Ireland's Network Strategy Implementation (NSI) Expansion Capacity project added capacity by re-purposing an existing manufacturing space for a new vaccine suite and a new multiproduct small-to-medium scale drug substance bioprocess suite at the Grange Castle plant in Dublin Ireland. Many thanks to Jim Brinkman and Phil Sumner for organizing.

Still to come.....

On September 30<sup>th</sup>, we will hold a unique joint pilot program with ISPE International and the DeVal chapter, to bring cost effective training on "Facility of the Future" to be hosted at Bristol-Myers Squibb in Plainsboro...stay tuned for more details.

On October 12<sup>th</sup>, we will hold a joint ISPE-IFM Golf outing at The Knoll Country Club in Parsippany. This will be a first for our two organizations to collaborate....stay tuned for more details.

A new and exciting year ahead....you should have received a voting request on the nominations for the **2015-2016 NJ Board of Directors.** We are thrilled to present these committed industry professionals who volunteer their efforts on behalf of their industry, companies, colleagues and students, they are:

**President - Paul Malinowski, Becton Dickson and Co.**  
**Vice President – Harry Segner, Genesis Engineers**  
**Treasurer – Jim Brinkman, Pfizer**  
**Secretary - Debra Bahr, Propharma**  
**Director, Vendor Representative - Raymond A. Roggero, CP Engineers**  
**Director, Engineering Representative – Christine Farner, Sanofi Pasteur**  
**Director, QC Representative – Thomas Flachmeyer, Prolong Pharma**  
**Director, YP Representative - Alok Bhatt, Bristol-Myers Squibb**  
**Director, Representative at Large - Anthony Hutchinson, Merck**  
**Director, Representative at Large - Frank DeMarinis, Purdue Pharma**  
**Director, Representative at Large - Rich Smith, Currie & Brown**  
**Director, Representative at Large - Philip Sumner, Pfizer**  
**Director, Representative at Large - Michael Kelliher, Genzyme**  
Please be sure to cast your votes by June 30<sup>th</sup>.

Also, I want to offer my most sincere thanks to the entire membership and in particular, the outgoing **2014-2015 NJ Chapter Board** for having given me the opportunity to serve you as President for the past year. I have been extremely fortunate to have collaborated with some of the finest professionals in the industry. Most of which are returning next year, but many thanks to:

**Vice President - Paul Malinowski, Becton Dickson and Co.**  
**Treasurer – Harry Segner, Genesis Engineers**  
**Secretary – Jim Brinkman, Pfizer**  
**Director, QC Representative - Debra Bahr, Propharma**  
**Director, Vendor Representative – Stephen Fowler, Process Equipment Resources**  
**Director, Engineering Representative – Norman Goldschmidt, Genesis Engineers**  
**Director, YP Representative - Shilan Motamedvaziri, Bristol-Myers Squibb**  
**Director, Representative at Large - David Kristjanson, Hollister Construction**  
**Director, Representative at Large - Frank DeMarinis, Purdue Pharma**  
**Director, Representative at Large - Rich Smith, Currie & Brown**  
**Director, Representative at Large - Philip Sumner, Pfizer**  
**Director, Representative at Large - Michael Kelliher, Genzyme**

Bye for now, thanks again and looking forward to many great things ahead!!!

Tony Crincoli  
President, ISPE NJ Chapter

## Chapter Sponsors

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## Newsletter Sponsor

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## Upcoming Events

### Vaccines and BioTech Double Header

June 23, 2015  
4:30 pm – 8:00 pm  
Pfizer – Peapack, NJ

#### Vaccines and Biologics Development

From the Bioreactor to the Patient, this is a nano course for ISPE NJ membership. Beginning with understanding the difference between drugs versus biologics, the presentation will review vaccine development, production case studies and clinical trials. A comparative review of biologic development and scale-up will highlight biologic product differences. The future of vaccines and biologics will be featured in the wrap up.

Presented by Dr. Dennis Gross, CEO Pennsylvania Drug Discovery Institute and past Dean of Thomas Jefferson University

#### Overall ISPE Facility of the Year Award Recipient and Category Winner for Operational Excellence

Learn how Pfizer Ireland's Network Strategy Implementation (NSI) Expansion Capacity project challenged the company to add capacity by re-purposing an existing manufacturing space for a new vaccine suite and a new multiproduct small-to-medium scale drug substance bioprocess suite at the Grange Castle plant in Dublin Ireland. The team utilized a Lean Management Strategy and a 5S program in the design process to ensure flow and operations. The project team also ensured the new manufacturing suites that included the latest technologies (i.e. EBR, PAT and Disposable Bag).

Presented by George Skillin, Senior Director, Pfizer Global Technology Services, Global Engineering

#### Schedule:

4:30 pm - 5:00 pm - Early Registration  
5:00 pm - 6:30 pm - Networking, Cocktails, Appetizers  
6:30 pm - 8:00 pm - Program  
8:00 pm - Adjourn

#### Registration:

ISPE NJ Member - \$75  
Non-Member - \$100  
ISPE Young Professional - \$40  
ISPE Student Member - \$10

### Facility of the Future

September 30, 2015  
Bristol-Myers Squibb – Plainsboro, NJ

### Golf Outing

October 12, 2015  
The Knoll Country Club – Parsippany, NJ

## Past Events

### Student Poster Competition – Johnson & Johnson, New Brunswick, NJ

April 2015

2015 ISPE Annual New Jersey Chapter Poster Competition Networking Dinner Meeting On April 28, 2015(3:00-8:00 pm) at Johnson & Johnson in New Brunswick, NJ. This annual event, held at different locations each year, permits our student members to compete, via poster presentation, for an opportunity to move on to the ISPE International Poster competition, held during ISPE Annual Meeting. The New Jersey Chapter students have historically been very successful at the national level and we hope they will continue the trend this year in Philadelphia. A record nineteen students competed in this year's contest. The schools represented were Rutgers University, New Jersey Institute of Technology, Manhattan College, Kingsbrough Community College and Stevens Institute of Technology. Our host this year was Mr. Jim Breen & Ms. Nandita Kamdar, of Global Engineering, Johnson & Johnson. The attendance of this event was around 100 New Jersey Chapter members, and other guests. Considering the record number of competitors, this year, the NJ Chapter selected total of top 4 graduate & undergraduate students versus top 2 every year! The winners are listed below. These Students will compete at the ISPE Annual Meeting in Philadelphia in November, 2015 against other ISPE Chapter and Affiliate poster contest winners.

2015 ISPE NJ Poster Winners:

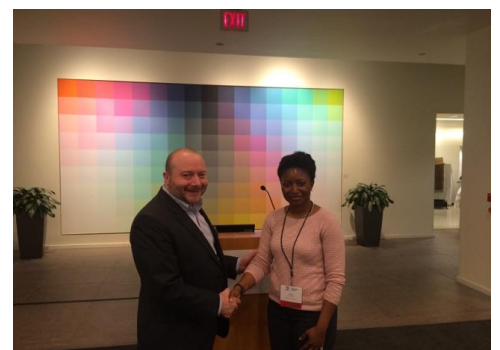
Sana Nasim – NJIT – Undergraduate  
Meng Li – NJIT – Graduate (PhD)  
Yingxi (Sally) Tang – NJIT – Graduate (MS)  
Maitraye Ren – Rutgers – Graduate (PhD)

We sincerely thank the industry representatives who spent all afternoon reviewing the posters and the student presentations. This year's Judging Panel included:

Regis Gautier, Roche  
Greg Cierpial, Bristol-Myers Squibb  
Greg Krupa, Merck  
Paul Malinowski, PE, Becton Dickinson and Co  
Rich McGreal, Merck  
Nishchal Chudasama, Bristol-Myers Squibb  
Mike Killiher, Genzyme  
Philip Sumner, Pfizer  
Tunde Babalola, Bristol-Myers Squibb

In addition to the posters, the evening included a great presentation by Dr. Nancy Barbour, Vice President – Drug Product Science and Technology, Bristol-Myers Squibb on “New Trends in Product Development”. Dr. Barbour presented the captive audience insights to evolving industry, product and regulatory landscape and emphasized how innovation is critical to success. She also enlightened the student groups on how various disciplines collaborate in the Pharmaceutical Industry.

This year, we also had a young professional who spoke to the students about her experience and journey from academic to professional career. Dr. Tunde Babalola, Associate Director, Compliance- Quality Operations, Bristol-Myers Squibb connected with students in this interactive session via her journey from a graduate student at Cornell to an upcoming leader at Bristol- Myers Squibb.



## Past Events

### Golf Outing – Neshanic Valley Golf Course, Neshanic Station, NJ

May 2015

On Monday May 18th the New Jersey Chapter held our annual golf outing and for the third time we returned to Neshanic Valley Golf Course in Neshanic Station, NJ in Somerset County. The weather cooperated and almost 80 golfers enjoyed a nice, but cool spring day. This year there were two additional activities that were new to our format. Ten new golfers participated in the shorter golfing format we introduced this year that included an hour of lessons from the Pro at the Callaway Golf Performance and Training Center located just adjacent to the main clubhouse. The lessons were followed by a round of nine holes on their executive par-32 course. It was a great opportunity for the group to become introduced to the game of golf and begin their journey of becoming scratch golfers!

The other program that we offered and apparently was a big hit, was a tour and tastings at two local vineyards. While they weren't Napa status vineyards the group that participated gave rave reviews of the quality of the wine and the charming nature of the facilities. The first vineyard they toured was Crossings Vineyard in Washington Crossing, PA and the second was Old York Cellars in Ringoes, NJ. This activity is sure to be on the agenda for next year, don't miss out.

The golfing and tours were capped off by an hour of networking with passed appetizers and drinks followed by dinner and the prizes for golfing and the raffles. It proved to be another successful and enjoyable golf outing for the Chapter. Thanks again to all our sponsors and volunteers who helped make this event successful.

Rich Smith and Dave Kristjanson



## Sponsorship and Advertising Opportunities

Advertising and sponsorship represent an excellent opportunity to be identified as an industry participant and a supporter of the ISPE New Jersey Chapter's Professional Programming. It is a particularly cost effective means of increasing your firm's visibility to the Chapter membership and beyond. ISPE NJC has many exciting sponsorship and advertising opportunities in 2015. These include:

### Chapter Sponsorship: \$1,650

Chapter Sponsorship has many benefits, including:

- Recognition as a Chapter Sponsor at all ISPE NJC events in 2015 (see fact sheet for details)
- Name and Logo on announcements for all ISPE NJC events in 2015 (see fact sheet for details)
- 1/2 page Advertising space in the ISPE NJC newsletter for 2015 (\$800 value!)
- 12 month Advertising space on the ISPE NJC website in 2015 (\$500 value!)
- Two complimentary tickets for all 2015 NJC Events<sup>1</sup> and additional attendees from your organization receive 10% off any event ticket cost.

### Advertising

Advertising opportunities are available for the Newsletter and Website "a la carte":

**Newsletter Advertising (2015-2016)** – The Chapter publishes a newsletter 4 times a year, highlighting recent and upcoming events, educational programs, technical articles and general interest of interest to the Members. The newsletter is published electronically to all current ISPE NJC Members and others on our circulation list. (5000+ recipients). Advertise for 1 issue or 4 consecutive issues:

Business Card size -	\$100 per issue or \$350 for 4 issues	(a \$400 value!)
1/4 page-	\$150 per issue or \$525 for 4 issues	(a \$600 value!)
1/2 page -	\$200 per issue or \$700 for 4 issues	(an \$800 value!)

**Website Advertising** – Your ad is visible to everyone who visits the ISPE NJC website.

6 months - \$275      12 months - \$500

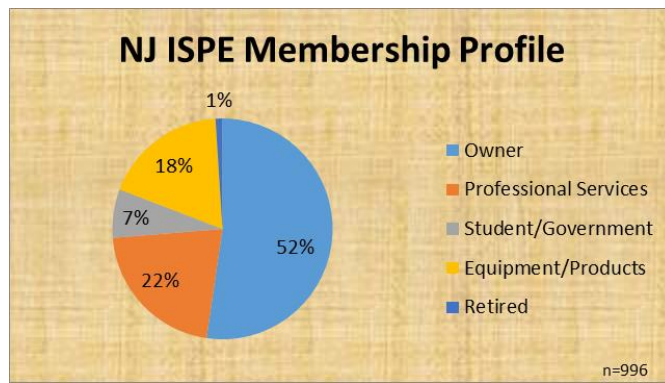
### Event/Program Sponsorship - (Opportunities start at \$125 depending on Event)

Event Sponsorship has many benefits, including:

- Name and Logo on all Announcements for designated event
- Recognition at Event during session
- Complimentary Tickets for Two Attendees<sup>1</sup>
- Select Event(s)- Vendor Table/Display (Professional Development Day and Golf Outing)

**Note 1- Golf outing complimentary tickets are limited to Clubhouse Outing activities only.**

To become a sponsor please visit - <http://www.eventbrite.com/e/2015-ispe-njc-chapter-sponsorship-advertising-program-tickets-14267028065> or contact [manager@ispenj.org](mailto:manager@ispenj.org)



### Did You Know???

Newsletter Distribution-

996 Members

5,387 Non Members

*Total Distribution to Owners, Professional Services, Equipment/Products Providers and Students located in: Alabama, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Indiana, Iowa, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Texas, Utah, Vermont, Wisconsin*

## ISPE NJ New Members: 2nd Quarter 2015

Welcome all 48 of our new Members!

Sara Alonso – Regeneron  
Jonathan Barber – Valeant Pharmaceuticals  
Nancy Belunis – Merck  
Eric Bergmann – EPIC-CSC Pharma Supply  
Consultants  
Franklin Bettencourt – Rutgers University  
Reena Colacot – Antares Pharma Inc  
Anne Coogan – Celgene Corporation  
Karen Crow – Unither Manufacturing LLC  
Michele Dalessandro – Merck & Co., Inc  
Paul Daly – Celgene Corp  
Alex Dean – City University of New York  
John Di Capua – Tishman Construction Corp  
Rebecca Doyle – Johnson & Johnson  
Monzer Elabbasi – Deloitte  
Raja Elangovan – Novel Laboratories, Inc  
Shun Yin Fong – Hovione LLC  
Zhaoxi Huang – Stevens Institute of Technology  
Lauren Jones – Regeneron Pharmaceuticals  
Subhodh Kumar Karkala – Rutgers University  
Alysmiriam Laboy – Johnson & Johnson  
Justin Lacombe – Teva  
Yidong Li – New Jersey Institute of Technology  
Michael Lynch – Lannett Company, Inc  
Jason Martin

Morven McAlister – Pall Corporation  
James McCann – Paragon Solutions  
Peter Mehlretter – Middough  
John Moses III – Merck  
Michael Myers – Zoetis Inc  
Sana Nasim – New Jersey Institute of Technology  
John Orzell – Bristol-Myers Squibb  
Savitha Panikar – Rutgers University  
Bhavyata Patel – Hovione  
Jeffery Pawar  
Jeffery Pistor  
Shakhnoza Rasulova – Stevens Institute of  
Technology  
George Ryder – Clear-Vu Lighting  
Lori Schneider – Bracco Diagnostics Inc  
Maitraye Sen – Rutgers University  
Narine Singh – Eli Lilly & Co  
Diana Smith – Celgene Corporation  
Douglas Standley – DPT Lakewood Inc  
Mani Sundararajan – Shire Pharmaceuticals  
Symon Syjongtian  
Lin Tan – Stevens Institute of Technology  
Jacob Varghese – Manhattan College  
Paul Vogel – Lachman Consultant Services  
Lu Zhang – New Jersey Institute of Technology



## 2015-2016 Election – ISPE New Jersey Board of Directors

Visit <https://www.surveymonkey.com/s/3LHMHYK> to read each candidate's bio sketch and vote for the 2015-2016 ISPE NJ Board of Directors.

Voting ends at 8:00 am Eastern time on Tuesday, June 30, 2015.

### 2015-2016 Candidate's

Paul Malinowski – President

Harry Segner – Vice President

Jim Brinkman – Treasurer

Debra Bahr – Secretary

Christine Farner – Engineering Representative

Ray Roggero – Vendor Representative

Tom Flachmeyer – QC Representative

Alok Bhatt – Young Professional Representative

Anthony Hutchinson – Representative at Large

Frank DeMarinis – Representative at Large

Rich Smith – Representative at Large

Mike Kelliher – Representative at Large

Philip Sumner – Representative at Large